EPO
Epidemiology Program Office
Issue 4

ADS Newsletter
Office of the Associate Director for Science
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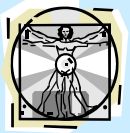

Policy and Guidance for Obtaining an OHRP-Approved Assurance (of compliance)

Any institution collaborating with CDC in human subjects research or using CDC funds for human subjects research must have an assurance for the Protection of Human Subjects approved by the Office for Human Research Protection (OHRP- DHHS).

What is an assurance?

An assurance (of compliance) is a signed agreement indicating an institution's commitment to adhere to ethical principles in human subjects research. This agreement {Federalwide Assurance (FWA) – see below} must be signed by an official legally authorized to represent the institution, and submitted to OHRP for approval. The agreement signifies adherence to the ethical principles designated by one of the following documents:

- *Declaration of Helsinki*
- *Council for International Organizations of Medical Sciences (CIOMS) International Ethical*

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Listing Affiliations

When works conducted during fellowship training are submitted for publication, appropriate program affiliations must be listed. If the work was done while on assignment, e.g., to another Center or a state health department, those affiliations should also be included. The following are appropriate formats for the programs listed:

Epidemic Intelligence Service (EIS)

- Epidemic Intelligence Service, Division of Applied Public Health Training, Epidemiology Program Office, CDC

Public Health Prevention Service (PHPS)

- Public Health Prevention Specialist, Division of Applied Public Health Training, Epidemiology Program Office, CDC

Prevention Effectiveness (PE)

- Steven M. Teutsch Post-doctoral Fellow in Prevention Effectiveness, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, CDC

Public Health Informatics (PHI)

- Public Health Informatics Fellowship Program
  Division of Public Health Surveillance and Informatics, Epidemiology Program Office, CDC

Preventive Medicine Residency (PMR)

- Preventive Medicine Resident (or Fellow), Division of Applied Public Health Training, Epidemiology Program Office, CDC

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Ethical Dilemmas in Public Health

Scenario 1 – A field assignee was contacted by a local hospital regarding an outbreak. The in-hospital collaborators expressed concerns about Freedom of Information Act (FOIA) issues because the assignee is a federal employee.

Issues - How should field assignees respond to hospital requests in regards to this particular issue?

The assignee should inform the hospital collaborator(s) that only records held at CDC or any other federal agency are subject to FOIA requirement. Federal assignees usually conduct investigations under the auspices of the state. Records are usually retained at the state.

Scenario 2 – A CDC field assignee wishes to conduct a study in a Native American community.

Issues – How can the assignee fulfill the public health objectives without stigmatizing the community?

The assignee has responsibilities to the public in general as well as to the community. In developing the study, the assignee must work with people who have experiences with vulnerable communities, and with community members to ensure that any proposed study is acceptable to the community. The Common Rule (Title 45 Code of Federal Regulation Part 46), which governs human subjects research, also provides additional protections to populations that are considered vulnerable, which includes economically disadvantaged communities or communities with a history of being discriminated against. Contact your supervisor or the EPO ADS Office if you need information and help on procedures to protect vulnerable populations.

Human Subjects Review Triage Form

The triage form should be used when submitting protocols to the Human Subjects Activity for IRB review. This checklist will help you identify areas of your protocol submission that you may have overlooked, without which your protocol may not be reviewed by IRB. The Triage form is being incorporated into the revised CDC forms 0.1250-0.1256. In the meantime, please include this form with your protocol submissions (http://intranet.cdc.gov/od/ads/hsrchklist.htm).

The Division ADS or designee is responsible for making sure that the Triage form is completed for each new protocol submitted to the EPO ADS office.

Items on the Triage form

1. Consecutively page-numbered protocol and attachments
   - **All** pages must be numbered, beginning with the title page of the protocol, followed by any consent form(s) and attachments.
2. Reading level and method(s) for consent form(s)
   - The reading level and method(s) must be stated for each consent form and should be at a level appropriate to the target population(s).
3. Scientific Ethics Verification (SEV) # for CDC Principal Investigator (PI) and all CDC co-investigators
   - The Scientific Ethics Verification # must be listed for all CDC co-investigators on the IRB form.
4. Waiver(s) properly justified for
   a. Informed consent
   b. Documentation of consent
   c. Parental permission
   - Any waiver(s) of informed consent, documentation of consent, or parental permission for research with minors, must be properly justified.

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EPO ADS Staff Update

Please join us in welcoming three new staff members to the EPO ADS office.

Sal Lucido recently joined EPO as CDC's lead for the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Sal has been with CDC for over a decade, most recently serving as a policy/legislative analyst with the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Sal was born in Gloucester, Massachusetts and grew up in Manchester, New Hampshire. He graduated from Stonehill College with a Bachelor of Arts in Political Science, Magna Cum Laude in 1989. In 1991, he earned a Master of Public Administration degree from the George Washington University and was accepted into the Presidential Management Internship Program (PMI). During his 2 year PMI experience, Sal served as a policy analyst with CDC's Office on Smoking and Health, HHS's Office of the Assistant Secretary for Legislation, and CDC's Office of Program Planning and Evaluation. Sal is currently a third year law student at Georgia State University's College of Law where he is a member of the Federalist Society, the Moot Court Honor Board, and a 2002-2003 Pupil with the Bleckley Inn of Court.

Linda Shelton recently joined EPO as a program analyst. Linda started working for CDC in 1985. She is originally from Baltimore, Maryland and has worked for the Social Security Administration as a cardpunch operator. She became an office supervisor for the Baltimore City Health Department, Division of Sexually Transmitted Disease (DSTDs) for 6 years. Serving in this capacity, she interacted with many public health advisors and other CDC personnel assisting in STD prevention and control efforts. She has also served as an epidemiology clerk. She decided to broaden her horizons by relocating to Atlanta and found a position with CDC as an administrative clerk and branch secretary for the center then known as the Center for Prevention Services (CPS), Training and Education Branch (TEB), Division of STDs. After 6 rewarding years working with public health advisors with a mission focused on STDs prevention and control, she decided to move on to the Human Resource Management Office (HRMO), where she worked in the following positions: personnel assistant, staffing assistant, human resource specialist. She devoted 11 years to this effort and made many contributions in the areas of recruitment, staffing, and customer services that were provided to CDC/ATSDR employees and the public.

Scott Kellerman will be joining EPO as the Deputy ADS in October. Born in Connecticut, Scott moved to St. Petersburg, Florida at 6 years of age. Scott graduated from the University of South Florida with a Bachelor's degree in Biology and the USF College of Medicine with a Doctorate in Medicine. After medical school, he pursued a pediatrics internship at the Case Western Reserve University Rainbow Babies and Children's hospital in Cleveland, OH. In 1994, he began EIS in the Hospital Infections Program, during which time he was accepted into the CDC Preventive Medicine Residency program and went on to receive a Masters of Public Health degree from Emory University. Upon completion of the degree, he finished the practicum year of the preventive medicine program at the Georgia state Division of Public Health in Atlanta. After graduation from the CDC residency program, he spent a year in the Hepatitis branch in NCID before going to the Surveillance Branch, Division of HIV/AIDS, NCHSTP, where he's spent the last 3 years.

The ADS Office would like to thank **Ed Maes** and **John Horan** for serving as Acting EPO ADS during Denise's maternity leave.

Frequently Asked Questions

1. What is the purpose of the EPO ADS mailbox (adsreview@cdc.gov)?

- The primary purpose of the EPO ADS mailbox is for submitting human subjects review number requests (HSR#) and general questions regarding human subjects research, the human subjects review process, and the IRB process.

2.Who should I contact about the status of my protocol or other IRB-related questions?

- Questions about a current IRB protocol should be directed to Aun Lor (alor@cdc.gov or 404-639-1488).

3. Who should I contact for questions about publications clearance?

- For general questions about the publications clearance process please contact Barbara Stallworth , (Bstallworth@cdc.gov or 404-639-3572), Office of Scientific & Health Communications (OSHC), EPO.
- For questions about the scientific clearance process in the EPO ADS Office please contact Linda Shelton (Lshelton@cdc.gov or 404-639-3683).

4. Who should I contact to discuss my clearance request that was not approved?

- First, check with your supervisor or Division ADS to clarify at what level the request was not cleared. If further questions remain after discussion with your division ADS, you may contact Denise Koo (Dkoo@cdc.gov) or Scott Kellerman (Skellerman@cdc.gov) in the EPO ADS Office at 404-639-3683.
- For clearance of Internet materials please contact Demetri Vacalis, OSHC, (Dvacalis@cdc.gov or 404-639-3183).

5. Who should I contact for questions regarding the Privacy Rule implementation at CDC?

- Contact Sal Lucido, CDC Privacy Rule Coordinator (Slucido@cdc.gov or 404-639-2219).

ADS Newsletter Survey

Please circle or write down your responses. Email your responses to Aun Lor (Alor@cdc.gov) or send an anonymous hard copy through interoffice mail to Aun at MS-C08. Thank you for your feedback.

1. Which division do you work in?

a. DAPHT
b. DPHSI
c. DPRAM
d. DIH
e. OSHC
f. OD

2. What is your job description/type? (Check all that apply)

❒ Scientist
❒ Public Health Advisor
❒ Analyst
❒ Administrative Staff
❒ Management
❒ Project officer
❒ Fellow
❒ Field Officer
❒ Others (Please indicate _____)

3. Have you been able to easily obtain copies of the EPO ADS Newsletters?

a. Yes
b. No
c. Have not seen the newsletter before

4. **Do you know where to find copies of current or back issues of the ADS Newsletters? (See EPO ADS intranet site below)**

a. Yes
b. No

5. How useful do you find the information contained in the ADS Newsletters?

a. Very useful
b. Useful
c. Not relevant to my work

6. Has the ADS newsletter been helpful in answering questions regarding science, policy, and other related issues?

a. Yes
b. No

7. What other topics would you like to see addressed in future issues?

8. Provide any other suggestions to improve the newsletter.

Assurance: Continued from page 1

Guidelines for Biomedical Research Involving Human Subjects
- *CIOMS International Guidelines for Ethical Review of Epidemiologic Studies*
- *Belmont Report (1974 – US)*
- *Title 45 Code of Federal Regulation Part 46 (AKA the Common Rule) for U.S. institutions*
- *Other appropriate statement of principles approved by OHRP*

Federalwide Assurance (FWA)

OHRP has implemented a new Federalwide Assurance (FWA) that covers an institution for 3 years for its human subjects research with any federal agency. The new FWA can be used for domestic and foreign institutions and is the recommended assurance, to replace the former Cooperative Project Assurances and Single Project Assurances. Therefore, OHRP is requesting that institutions apply for a FWA as soon as possible. (However, existing Cooperative or Single Project Assurances will remain in effect until their designated expiration date, or December 31, 2003, whichever comes first).

1. Any institution can apply for a FWA without prior approval or recommendation by CDC or any other DHHS agency.
2. FWA applications should be signed by a legally authorized official and sent directly to OHRP by the institution.
3. The institution applying for an FWA does not have to have its own IRB, but if none exists it must designate an OHRP-approved IRB from another institution before applying for an FWA.
4. The FWA is not protocol-specific, nor does a protocol or study need to be in place or be in preparation before an institution can apply.

All CDC IRB submission forms require the investigator to furnish OHRP-approved assurance numbers, if already obtained by the collaborating institution(s). If not, the Principal Investigator should request that the collaborating institution(s) apply for an FWA. A protocol may be submitted to the IRB before the assurance is in place, but the project cannot begin until the signed assurance is approved by OHRP. Once the assurance is in place and the protocol has been approved by the appropriate IRBs, the PI will receive an IRB approval letter from CDC Human Subjects Activity (HSA).

Note that OHRP will not accept assurance applications submitted only in a foreign language; therefore, an English version must accompany any signed translated assurance. CDC can provide French and Spanish translations if needed. For complete instructions and applications, visit the OHRP website (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm).

Contact Virginia Talley, Assurance Coordinator, Human Subjects Activity, CDC Office of the Associate Director for Science, at (404) 639-4026 for more information and help in obtaining assurance.

Affiliations: Continued from page 1

CDC Knight Journalism

- CDC Knight Journalism Fellowship Program, Epidemiology Program Office, CDC

Include other affiliation(s) when applicable, for example:

- When assigned to another center
  - ➢ Viral Gastroenteritis Section, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, CDC
- When assigned to a state
  - ➢ Bureau of HIV/AIDS, Division of Disease Control, Florida Department of Health

Triage: Continued from page 2

5. Vulnerable populations properly addressed
   a. Children
   b. Pregnant women
   c. Prisoners

   - Participation of any member of a vulnerable population in the study must be addressed and additional protection procedures described when appropriate.

6. CDC investigator(s)'s roles(s) described

   - The role of all CDC investigators must be described in the study protocol.

7. Protocol specifics (questionnaires, assent forms, focus group scripts) included

   - The protocol must include all documents relevant to the study, e.g. study questionnaires, consent and assent form, focus group scripts.

8. If study involves HIV testing of linked specimens, will results be given to subjects? If not, please address the Public Health Service policy on notification of HIV test results.

9. Suggested level of risk

   - Determine the level of risk, minimal or greater than minimal, as described in the Common Rule.

10. Suggested expedited category(ies)

    - Assess whether the protocol falls into one or more of the 9 expedited categories described in the Common Rule.

11. Possible reason(s) for sending to full IRB

    - List reason(s) for sending the protocol to the Full IRB board.

Contact Aun Lor (alor@cdc.gov or 404-639-1488) for information or questions.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Update

CDC's Privacy Rule activities began in earnest in August with the hiring of Sal Lucido as the Privacy Rule Coordinator. EPO OADS also hired Linda Shelton to provide partial support to the Privacy Rule project as well as OADS generally. There have been a number of significant accomplishments associated with the project over the initial 2 months of effort.

Privacy Rule Working Group

After completing a series of one-on-one meetings with representatives from each CIO, OADS established the CDC Working Group on Privacy. The working group comprises over 20 people with representation from every CIO at CDC. Based on initial discussions, the working group agreed to a set of working objectives and goals. The objectives of the work group include (a) assuming leadership for defining the nature of the Privacy Rule as it relates to public health programs, (b) establishing an industry-wide understanding of the actual impact of the privacy rule on public health programs, and (c) evaluating the impact of the Privacy Rule on public health programs. A key component of this effort will be the development and provision of technical assistance materials for CDC employees and partners. The working group will be meeting on a monthly basis to track progress, share experiences, and delegate responsibilities to group members.

Technical Assistance Training

In addition to the establishment of the work group, OADS launched a Privacy Rule Website on the CDC intranet. This site (http://intranet.cdc.gov/epo/ADS/Privacy-Rule-Homepage.htm) is located on the EPP OADS website and provides visitors with important information on the Privacy Rule and public health. The site includes a reading room of information on the Privacy Rule, including presentations that can be used by visitors to learn more about the privacy rule. This reading room also contains a number of PowerPoint presentations developed to explain the public health implications of the Privacy Rule. The site also contains CDC's first effort to compile a set of FAQs addressing public health and the privacy rule. CDC Office of General Counsel (OGC) reviewed and cleared the FAQs before posting them on the website. The FAQs are general in nature and OADS expects this section of the website to expand as additional program questions are submitted and responded to by OGC and OADS. OADS plans to develop a similar Internet site accessible to CDC partners in the near future.

In addition to the website, CDC staff remain active in the Department of Health and Human Service (DHHS) Privacy Committee as well as the HIPAAGives (Government Information Value Exchange for States) (www.hipaagives.org) organization. Participation in both these groups helps us to facilitate communication between HHS and state and local health departments. Examples of these intermediary efforts include (a) the general release of Office of Civil Rights' (OCR) decision flow chart for determining whether a government organization is a covered entity, (b) the coordination of a CDC presentation on the Privacy Rule and immunization registries, and (c) the utilization of HIPAAGives as a forum for providing the HHS Privacy Committee and OCR with feedback regarding the implementation concerns of state and local health departments.

CDC staff have also taken advantage of a number of training opportunities over the last month. CDC representatives attended the OCR training on the Privacy Rule that addressed a number of general topics including public health programs. This forum gave us an opportunity a) to establish valuable linkages between OCR and CDC on this issue, b) to communicate concerns to OCR regarding the Privacy Rule. CDC researchers attended a National Institutes of Health (NIH) meeting dedicated to the Privacy Rule and research. NIH convened the meeting in an effort to develop technical assistance materials for researchers on the privacy rule. As a result of this meeting, CDC researchers initiated a dialogue with the CDC ADS on efforts to educate the research community on the Privacy Rule. Finally, NCCDPHP Division of Reproductive Health sponsored a presentation by Dr. Mark Rothstein on the Privacy Rule. CDC publicized it to working group members, envisioned it to Hyattsville, and videotaped the presentation for future use.

OADS staff are currently developing at-a-glance information briefs to address the Privacy Rule generally as well as the covered entity status in relation to state and local health departments. OADS expects to post the "at-a-glance" on the intranet site as soon as the documents are in final form.

Ongoing Training

OADS conducted preliminary discussions with staff from the PHPPO-funded Center for Law and the Public's Health regarding the development of technical assistance materials on public health and the Privacy Rule. The discussion focused on (a) the development of lay-persons guide to Privacy Rule implementation, (b) organizing a symposia to release the guide, (c) convening a consensus meeting between representatives of public health and covered entities to establish a consensus statement regarding post-implementation relations between public health entities and covered entities.

Finally, a longer-term goal is the development of an assessment strategy for analyzing the impact of the privacy rule on public health. Through this strategy, CDC will identify the detrimental impacts of the Privacy Rule and develop policy recommendations related to Privacy Rule revisions. CDC expects to use these recommendations in ongoing discussions with OCR on the Privacy Rule and public health.

Contact Sal Lucido, Privacy Rule Coordinator, at 404-639-2219 or Slucido@cdc.gov for information or questions.